K031954 1 of 2

AUG 21 2003

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the CoolTouch CT3 laser systems is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92 and 21 CFR § 807.93 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) Summary.

Applicant: New Star Lasers, Inc. d.b.a. CoolTouch Incorporated

Address: 9085 Foothills Blvd.
Roseville, CA 95747

Company Contact: Donald V. Johnson
Vice-President, Operations

Telephone: (916) 677-1912
(916) 677-1901 (FAX)

Date Summary Prepared: June 24, 2003

Device Name: CoolTouch Incorporated Model CT3
Laser Systems

Common Name: Laser Instrument, Surgical Laser System and Accessories

Classification Name: Instrument, Surgical, Powered Laser
21 CFR § 878.4810
Product Code: GEX

Predicate Device: CoolTouch Incorporated "CoolTouch" and "CoolTouch II" Nd:YAG Laser Systems

Device Description: The CoolTouch Incorporated CoolTouch CT3 Nd:YAG Surgical Lasers are lasers producing emissions at 1320nm. The lasers consist of several interconnected sections: the *cabinet*, which houses the power supply, cooling system, microcontroller, and the laser head, the *fiber optics*, and the *handpiece*. The systems provide safety features that are designed to protect the user and patient from high voltages and laser emissions.

Intended Use/Indications:

The CoolTouch CT3 ND:YAG Laser System is indicated for treatment of back acne and treatment of atrophic acne scars

Performance Standards: The CoolTouch CT3 laser systems comply with the appropriate sections of 21 CFR §1010 and 21 CFR § 1040.

Substantial Equivalence Statement:

Based on the information in the premarket notification, CoolTouch Incorporated believes that the CoolTouch CT3 Nd:YAG laser systems are substantially equivalent to the cited legally marketed predicate device for the indications requested.

June 24, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Mr. Donald V. Johnson
Vice President, Operations
CoolTouch Incorporated
9085 Foothills Boulevard
Roseville, California 95747

Re: K031954
Trade/Device Name: CoolTouch Incorporated Model CT3 Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 24, 2003
Received: July 1, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K031954

Device Name: CoolTouch Incorporated Model CT3

Indications for Use Statement:

The CoolTouch CT3 Laser System is indicated for:

1. **treatment of back acne**
2. **treatment of atrophic acne scars.**

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031954